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10/790,025

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/790,025 | Applicant(s) VEASEY ET AL. | |
| | Examiner SHEFALI D. PATEL | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004 and 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9,10,16 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,11-15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/28/2004,01/19/2005,06/01/2005,07/22/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 19-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention II, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on October 5, 2007.

2. Claims 5, 6, 10, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Species II, III, and IV, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/30/2007.

Applicant's election with traverse of Species I (Figures 1-5) in the reply filed on November 30, 2007 is acknowledged. The traversal is on the ground(s) that the Examiner will not be unduly burdened by searching the dependent claims that do not read on the elected species. This is not found persuasive because the dependent claims 5, 6, 9, 10, and 16, drawn to Species II-IV, require a different field of search than Species I. As part of a different field of search, a search for Species II-IV would employ different search queries than that of Species I: With respect to claim 5, Species I does not require a boss on a second side of the insert. With respect to claim 6, Species I does not require a boss on a second side of the insert, wherein the boss has a radial flange. With respect to claims 9 and 10, Species I does not require rigid keying of the portions of the dose dial sleeve together. With respect to claim 16, Species I does not require the piston rod to be generally U-shaped.

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Further, Applicant elected claim 9 are readable upon elected Species I (Figures 1-5). However, the rigid keying of the portions of the dose dial sleeve together, as described in claim 9, is a characteristic of non-elected Species II (Figure 6) (Specification, page 13, lines 5-10). Therefore, Examiner is withdrawing claim 9 from consideration.

Currently, claims 1-4, 7, 8, 11-15, 17, and 18 are under examination.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: GB 0304823.8, filed in Great Britain, on March 3, 2003.

Drawings

4. The corrected replacement drawings (Figures 1-10) were received on March 7, 2008. These drawings are acceptable.

Specification

5. The abstract of the disclosure is objected to because of the following:

Applicant is reminded of the proper language and format for an abstract of the disclosure:

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "**means**"

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and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the abstract, the following instances of **"means"** have been found:

- a. **means** for selecting a dose of medicinal product to be expelled
- b. **means** for expelling the selected dose of medicinal product
- c. The housing may be a unitary housing within which the **means** for selecting a dose and the **means** for expelling the selected dose are moveably retained
- d. ratchet **means**
- e. clutch **means** which upon depression of the button prevents rotation between the dose dial sleeve and the drive sleeve

Correction is required. See MPEP § 608.01(b).

- 6. The disclosure is objected to because of the following informalities: the specification does not contain section headings.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

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- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

7. Claims 2 and 7 are objected to because of the following informalities:

In regards to claim 2, the uses of "piston" should be replaced with "piston rod" as the "piston" is a separate feature characteristic to the cartridge (Specification, page 6, lines 25-26).

In regards to claim 7, the word "include" should be replaced with "including" (page 5, line 1).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 8, claim 8 recites the limitation "**the cylindrical portion** of the insert" in page 5, line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, 7, 8, 11-15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Moller (US 2002/0052578).

In regards to claim 1, Moller teaches a pen-type injector (Figures 1-2) comprising:

- a. a housing (housing [1])
- b. a cartridge (ampoule, not shown) containing medicinal product, the cartridge being retained within the housing [1] (paragraph [0022])
- c. means for selecting a dose of medicinal product to be expelled (dose setting drum [17])
- d. means for expelling the selected dose of medicinal product (tubular part [20])
- e. characterized in that the housing [1] comprises a unitary housing within which the means for selecting a dose of medicinal product to be expelled [17] and the means for

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expelling the selected dose of medicinal product [20] are moveably retained (paragraphs [0025][0026])

In regards to claim 2, Moller teaches a pen-type injector (Figures 1-2) comprising:

- a. a housing (housing [1])
- b. a piston rod (threaded piston rod [4]) having a screw thread
- c. an insert (partitioning wall [2], tubular element [5], connection bars [12]) located in the housing [1] and through which the piston rod [4] may rotate (Figure 1)
- d. ratchet means (nut [13]) associated with the insert to ensure the piston rod [4] only rotates in a single direction through the insert (paragraph [0024])
- e. a dose dial sleeve (dose setting drum [17]) rotatable with respect to the housing [1] and the insert
- f. a drive sleeve (tubular part [20]) which is axially displaceable but not rotatable with respect to the piston rod [4]
- g. a button (button [18]) located on the drive sleeve [20] and rotatable with respect to the drive sleeve (paragraph [0029])
- h. clutch means (coupling [21]) which upon depression of the button [18] prevents rotation between the dose dial sleeve [17] and the drive sleeve [20] (paragraph [0029])

In regards to claim 3, Moller teaches that the injector further comprises a nut (ring [25]) which is rotatable with respect to the drive sleeve [20] and axially displaceable but not rotatable with respect to the dose dial sleeve [17] (paragraph [0027]).

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In regards to claim 4, Moller teaches that the insert comprises a web [2] having an opening (central opening, not referenced), the web [2] being a first cylindrical portion, a second cylindrical portion [5] extending from a second side of the web, and a third cylindrical portion [12] extending from a second side of the web.

In regards to claims 7 and 8, Moller teaches that the dose dial sleeve [17] comprises a first section of first diameter, the first section including interengaging features to provide a helical thread (internal thread, not shown, and outer thread [7]) between the insert and the dose dial sleeve (paragraph [0025]).

In regards to claim 11, Moller teaches that an outer surface of the dose dial sleeve [17] includes graphics (numbers on a helical scale, not shown) and wherein the housing [1] is provided with a window (window, not shown) through which a portion of the graphics may be viewed (paragraph [0025]).

In regards to claim 12, Moller teaches that the drive sleeve [20] comprises a first part of first diameter located between the insert [2] and the piston rod [4] and a second part of second diameter located between the piston rod [4] and the dose dial sleeve [17], an internal surface of the drive sleeve [20] being splined to the piston rod [4] such that relative rotation between the drive sleeve and the piston rod is prevented while longitudinal displacement is permitted (Figure 1) (paragraph [0033]).

In regards to claims 13 and 15, Moller teaches that the drive sleeve [20] further comprises a central receiving area having a peripheral recess (Figure 1), and wherein the button [18] being

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of generally "T" shaped configuration has a stem that is retained within the receiving area by co-operation between a peripheral bead [33] provided on the stem retained in a peripheral recess [32] provided in the central receiving area (Figure 1) (paragraphs [0029][0033]).

In regards to claim 14, Moller teaches that the nut [25] is provided on a helical thread provided on the drive sleeve [20] and is located between the drive sleeve [20] and the dose dial sleeve [17], the dose dial sleeve and the nut being splined together by spline means (spring [26]) to prevent relative rotation between the nut and the dose dial sleeve (paragraph [0027]).

In regards to claim 17, Moller teaches that the clutch means [21] comprises a plurality of radially extending longitudinally directed teeth (protrusions [32][33]) provided respectively on the dose dial sleeve [17] and the drive sleeve [20] (paragraph [0029]).

In regards to claim 18, Moller teaches that clicker means are provided between the dose dial sleeve [17] and the drive sleeve [20], the clicker means comprising a plurality of longitudinally extending teeth (rosette of V-shaped teeth of drive sleeve [20], not referenced) and a flexible toothed member (teeth [24]), wherein relative rotation between the dose dial sleeve and the drive sleeve causes the flexible toothed member to ride over the teeth to produce a series of clicks (paragraphs [0027][0029]).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Sams (US 2003/0050609), Burroughs et al (US 6,221,046), Steinfeldt-Jensen et al (US 6,235,004), Harris (US 5,226,895), Chanoch (US 5,674,204), Pawelka et al (US 5,584,815).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

10/06/2008

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767